DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 18, 2014

Lightlab Imaging, Inc.
% Jeffrey Roberts
Principal Regulatory Specialist
4 Robbins Road
Westford, MA 01886

Re: K141769
Trade/Device Name: Optis Integrated System, Dragonfly Optis Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, NQQ
Dated: June 30, 2014
Received: July 1, 2014

Dear Jeffrey Roberts,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

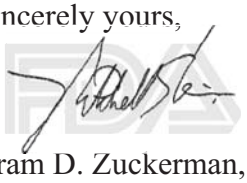
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: OPTIS Integrated System

Indications for Use:

The OPTIS Integrated System with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The OPTIS Integrated System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

Prescription Use __X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

for the LightLab Imaging, Inc.
OPTIS Integrated System
and
Dragonfly OPTIS Imaging Catheter
(per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

LightLab Imaging, Inc.
4 Robbins Road
Westford, MA 01886

Contact Person: Jeffrey Roberts
Telephone: 978-577-3451

Date Prepared: 6/30/14

2. DEVICE NAME

Proprietary Name:	OPTIS Integrated System
Common/Usual Name:	Ultrasonic pulsed echo imaging system
Classification Name:	Ultrasonic pulsed echo imaging system

Proprietary Name:	Dragonfly OPTIS Imaging Catheter
Common/Usual Name:	Diagnostic Intravascular Catheter
Classification Name:	Diagnostic Intravascular Catheter

3. DEVICE CLASSIFICATION

The OPTIS Integrated System medical device comprises the following:

Classification Name	Ultrasonic Pulsed Echo Imaging System
Classification Regulation	21 CFR 892.1560
Product Code	NQQ

The Dragonfly OPTIS Imaging Catheter device comprises the following:

Classification Name:	Diagnostic Intravascular Catheter
Classification Regulation:	21 CFR 870.1200
Product Code:	DQQ

4. PREDICATE DEVICE

- ILUMIEN OPTIS with Dragonfly I Catheter manufactured by LightLab Imaging, Inc. K123369

5. DEVICE DESCRIPTION

The OPTIS Integrated System performs optical coherence topography (OCT) and fractional flow reserve (FFR) procedures and provides images of the coronary arteries in patients who are candidates for transluminal interventional procedures. The device utilizes fiber-optic technology to emit near infrared light and receive light reflected from coronary tissue in order to produce high resolution, real time images. The imaging engine generates wavelength scanning light, which is guided to the DOC and the catheter. The reflection is collected and sent back to the engine. The engine processes the optical signal and converts it to electrical signal, which is then fed into the Host PC. The software application processes the signal and generates OCT images. The devices is compatible with Dragonfly OPTIS, Duo, and I imaging catheters, in addition to the PressureWire Aeris.

The Dragonfly OPTIS Imaging Catheter is a sterile, single-use intravascular catheter consisting of a catheter body external sheath and an internal rotating fiber optic imaging core. The external sheath serves two primary functions: 1) to facilitate placement of the device into the coronary artery and 2) to cover and protect the inner rotating fiber optic imaging core.

The inner rotating fiber optic imaging core emits near infrared light to the tissue and receives reflected light. It is driven by a stainless steel torque wire visible under fluoroscopy and pulled back through the window tube of the external sheath by the DOC. The emitted and returned reflected light are combined and processed by the OPTIS Integrated System software to construct an OCT image. The patient is never exposed to moving parts as the external sheath completely covers the rotating imaging core.

6. INTENDED USE

The OPTIS Integrated System with C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The C7 Dragonfly, Dragonfly

DUO, or Dragonfly OPTIS Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The C7 Dragonfly, Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The OPTIS Integrated System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

OPTIS Integrated System

The OPTIS Integrated System is equivalent to the ILUMEIN OPTIS predicate device in that both devices perform optical coherence tomography (OCT) and fractional flow reserve (FFR) procedures and provide images of the coronary arteries in patients who are candidates for transluminal interventional procedures. Both devices utilizes fiber-optic technology to emit near infrared light and receive light reflected from coronary tissue in order to produce high resolution, real time images. The imaging engine in both devices generates wavelength scanning light, which is guided to the DOC and the catheter. The reflection is collected and sent back to the engine. The engine processes the optical signal and converts it to electrical signal, which is then fed into the Host PC. The software application processes the signal and generates OCT images. Both devices are compatible with Dragonfly OPTIS, Duo and I imaging catheters, in addition to the PressureWire Aeris.

The OPTIS Integrated System configuration has been modified from the ILUMIEN OPTIS predicate device to accommodate the integration of the device into a single catheterization lab. The modification includes providing components equivalent to the ILUMIEN OPTIS predicate device and includes 4 additional main hardware components built into the catheterization lab. The 4 additional main hardware components include a System Cabinet, Remoting Cable, DOC Holster and Tableside Controller. This integrated configuration incorporates a control room monitor, keyboard and mouse location and video connection/switching. The engine design has been modified to work with the integration architecture. The software has been upgraded to revision E.1 for the following features:

- OPTIS Integrated System Configuration
- Angio Co-Registration

- Curtain GUI interface
- Dragonfly OPTIS Imaging Catheter Support
- Continuous calibration for window tube
- DICOM modality integration
- Manual pull back triggering
- Catheter user connection interface
- Improved acquisition workflow display

Dragonfly OPTIS Imaging Catheter

The Dragonfly OPTIS Imaging Catheter is equivalent to the predicate device in terms of hardware components and operational use. They both are comprised of a catheter body external sheath and internal rotating fiber optic imaging core which emits near infrared light to the tissue and receives reflected light. They both are driven by a stainless steel torque wire by the DOC which is connected to the OCT Imaging system. They are both purged through the central catheter with 100% contrast media prior to use. In both the Dragonfly OPTIS Imaging Catheter and the predate device emitted and returned reflected light are combined and processed by the system software to construct an OCT image.

The Dragonfly OPTIS Imaging Catheter represents an upgrade to the predicate device in terms of performance through the same operational characteristics, and fundamental technological characteristics to include the following:

- Multilayer window tube
- Flexible proximal end
- Improved break away joint
- Improved purge tube
- Dual lumen tip
- High speed proximal end
- 155µm fiber
- RFID.

8. PERFORMANCE TESTING

The OPTIS Integrated System has been tested and is in compliance with IEC 60601-1:2005 + A1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, • IEC 60601-1:2005 + A1: 2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, IEC 60825-1:2nd Ed. 2007 Part 1: Equipment classification and requirements, IEC 62366:2007 Medical devices – Application of usability engineering to medical devices, IEC 60601-1-6:2010 Medical

electrical equipment – Part 1-6: General requirements for basic safety and essential performance, IEC 60601-2-18:2009 Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment, 21 CFR 1040.10 Performance Standards for Light Emitting Products, sections b5 and b15 and IEC 60601-1-2 Ed. 2.1, Electromagnetic emissions and immunity requirements for medical electrical equipment – Group 1 Equipment, Class B for non-life supporting equipment.

In addition to the electrical safety testing performed, software verification and validation was conducted to FDA regulations, standards and guidance document requirements. The results of this testing conclude the software has met these requirements. Design verification and validation was also performed on the OPTIS Integrated System and Dragonfly OPTIS Imaging Catheter in compliance with internal design control procedures which included bench testing and pre-clinical animal testing. The results of this testing concludes the OPTIS Integrated System and Dragonfly OPTIS Imaging Catheter is determined to be safe and effective and is substantially equivalent to the ILUMIEN OPTIS predicate device.